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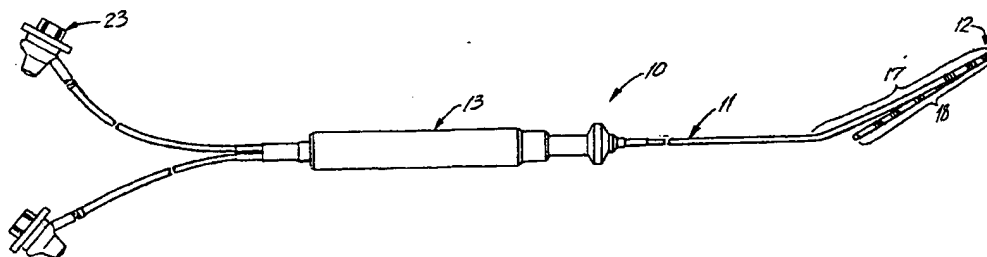
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Published*With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*(54) Title: **ELECTROPHYSIOLOGY CATHETER WITH PRE-CURVED TIP****(57) Abstract**

An electrode catheter (10) for mapping right sided supra-ventricular accessory electrical pathways comprises an elongated tubular catheter body (11) and a tip portion (12) which comprises a compound curve. The plane of the compound curve lies transverse to and preferably at an angle of about 30° to the axis of the catheter body (11). The compound curve carries a plurality of electrodes (21). A puller wire (30) extends through the catheter body (11) and into the tip portion (12), the distal end of the puller wire (30) being fixedly attached to the distal end of the tip portion (12). A handle (13) is provided at the proximal end of the catheter (10) for controlling longitudinal movement of the puller wire (30) relative to the catheter body (11). Proximal movement of the puller wire (30) to the catheter body (11) results in the angle of the first bend becoming more acute and a decrease in the diameter of the generally circular curve of the tip portion (12).

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ELECTROPHYSIOLOGY CATHETER WITH PRE-CURVED TIP**Field of the Invention**

15 This invention relates to an electrophysiology mapping catheter having a precurved tip and more specifically to an electrophysiology mapping catheter having a generally circular tip portion, the diameter of which can be adjusted by manipulation of a puller wire.

Background of the Invention

20 Millions of people suffer from abnormally high heart beat rhythm, a condition referred to as "tachycardia." One type of tachycardia is right sided supra-ventricular tachycardia (SVT). This condition is caused by a conducting pathway between the right atrium at the right ventricle across the tricuspid annulus. With right sided supra-ventricular tachycardia, the atria typically beats too rapidly. Symptoms of right sided supra-ventricular tachycardia include chest
25 pain, fatigue and dizziness.

Radiofrequency (RF) catheter ablation has been found to be a safe and efficacious means of interrupting accessory electrical pathways which result in tachycardia. In such a procedure, a special electrophysiology catheter is guided through a vein into the patient's heart and to the site of the accessory pathway.
30 The catheter is designed to transmit energy from an external source into the accessory pathway in an amount sufficient to ablate the tissue. The ablated tissue is replaced with scar tissue which interrupts the accessory pathway. The normal conduction of electroactivity is thereby restored.

Before an RF catheter ablation procedure can be utilized, the site of the
35 accessory pathway must be determined. This is accomplished with a diagnostic or mapping catheter which typically comprises multiple electrodes for stimulating and sensing electrical activity. In, general, this procedure involves introducing

1 a mapping catheter into the patient's heart and into the chamber where the
arrhythmia condition exists. The tissue is stimulated in a manner intended to
induce the arrhythmia and expose the abnormal electrical conduction. The
5 resulting information regarding the number and locations of aberrant sites
identified and the severity of the abnormality enables the electrophysiologists to
determine the appropriate course of treatment. Electrophysiologic evaluation
generally involves multiple tests to diagnose the arrhythmia and to assess the
potential effectiveness of various treatment strategies.

10 One procedure for determining the site of right sided supra-ventricular
tachycardia is to introduce a mapping catheter into the right coronary artery
which extends about the right atrium at about the location of the tricuspid
annulus. This procedure is very dangerous and accordingly not favored. Another
known procedure is to introduce a deflectable tip mapping catheter into the right
15 atrium and, by manipulation of the catheter, to move the catheter about,
particularly around the tricuspid annulus until the accessory pathway is located.
This is a time-consuming and cumbersome approach.

20 An improvement in mapping the right sided supra-ventricular pathways
has been the use of a multiple electrode catheter having a generally circular
precurved tip portion. Such a catheter is advanced from the femoral vein by
Seldinger technique into the right atrium. The distal end of the tip portion is
maneuvered into the coronary sinus (C.S.) ostium and the remainder of the
circular tip portion is maneuvered into the region of the tricuspid annulus.
Through the use of multiple electrodes around the circular tip portion, the time
required to map the right sided supra-ventricular pathways is greatly reduced.

25 While the use of a generally circular tip portion has greatly improved the
efficiency of the mapping procedure for right sided supra-ventricular pathways,
there are still some difficulties associated with this procedure. First, the circular
tip portion of the catheter is difficult to maneuver. Secondly, the diameter of the
generally circular tip portion is fixed and therefore cannot be adjusted to
30 accommodate atrial chambers of varying sizes. The catheter tip is also difficult
to maneuver, particularly being difficult to anchor the distal end of the tip portion
in the CS ostium.

Summary of the Invention

35 This invention provides an improved electrode mapping catheter
particularly suitable for mapping right sided supra-ventricular accessory electrical
pathways in the heart. The catheter comprises an elongated, flexible tubular

1 body having proximal and distal ends. The wall of the catheter body is preferably reinforced with one or more layers, reinforcing, e.g., layers of braided stainless steel mesh.

5 Extending from the distal end of the catheter body is a tubular tip portion. The tip portion comprises a generally circular curve transverse to the axis of the catheter body. In a preferred embodiment, the tip portion comprises a compound curve including a first bend of about 30° to the catheter body axis and then a generally circular curve lying in a plane about 30° to the catheter body axis.

10 A puller wire extends through the catheter body and into the tip portion. The distal end of the puller wire is fixedly attached to the wall of the tip portion adjacent the distal end of the tip portion. The proximal end of the puller wire is connected to a handle which provides means for moving the puller wire longitudinally relative to the catheter body. Movement of the puller wire proximally relative to the catheter body results in a decrease in the diameter of the generally circular section of the tip portion and increase in the angle of the plane of the circular tip portion to the axis of the catheter body to more than 30° .

20 The section of the tip portion comprising the generally circular curve carries a plurality of electrodes spaced apart from each other. An electrode lead wire is connected at its distal end to each electrode and extends through the interior of the tip portion and catheter body. At their proximal ends, the electrode lead wires terminate in a suitable connector for connection with a stimulator and/or recorder.

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1 **Brief Description of the Drawings**

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

5 FIG. 1 is an external view of a preferred electrode catheter constructed in accordance with the present invention;

FIG. 2 is an enlarged end view of the catheter tip portion;

FIG. 3 is an enlarged end view of another embodiment showing the catheter tip portion of another embodiment of the invention;

10 FIG. 4 is a side view of the tip portion of the catheter of FIG. 1;

FIG. 5 is a side view of the tip portion shown in FIG. 4; after the puller wire has been moved longitudinally proximally with respect to the catheter body;

FIG. 6 is a fragmentary enlarged view of a portion of the tip portion showing an electrode pair;

15 FIG. 7 is a cut-away view of a heart showing the positioning of the tip portion about the annulus of the tricuspid valve;

FIG. 8 is a preferred form used in the formation of the compound curve of the tip portion; and

20 FIG. 9 is an enlarged cross-sectional view of the distal end of the tip portion.

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1 Detailed Description

FIGS. 1 and 2 illustrate a preferred electrode catheter constructed in accordance with the present invention. The electrode catheter 10 comprises an elongated catheter body 11 having proximal and distal ends, a catheter tip
5 portion 12 having a generally circular curve transverse, i.e., at an angle to the axis of the catheter body 11 at the distal end of the catheter body 11, and a control handle 13 at the proximal end of the catheter body 11.

The catheter body 11 comprises an elongated tube having a lumen 15. The catheter body 11 is flexible, i.e., bendable, but substantially
10 non-compressible along its length. The catheter body 11 may be of any suitable construction and made of any suitable material. A presently preferred construction comprises a nylon tube surrounded by one or more reinforcing layer of braided stainless steel or the like with a polyurethane coating.

The length and diameter of the catheter body 11 are not critical. For the
15 electrode catheter shown in the accompanying drawing, a length of about 40 to 48 inches, an outer diameter of about 0.1 inch (8 French), and an inner diameter, i.e., lumen diameter, of about 0.03 to about 0.04 inches is presently preferred.

The catheter tip portion 12 comprises a short length, e.g., 8 inches in length and diameter size of 6½ French, of flexible tubing having a lumen 16.
20 The tip portion 12 is formed in a compound curve comprising a first section 17 forming a bend of preferably about 30°, and a second section 18 forming a generally circular curve. Such a compound curve results in the generally circular curve lying generally in a plane transverse to, and preferably about 30° to, the axis of catheter body 11.

As used herein, a "generally circular curve" is meant to include curves
25 which are in and out of a simple plane, spirals, helices, non-circular loops and the like. Such curves may form a full 360° circle or more, but may also be less than a full circle. It is preferred that such curves form at least a semi-circle, i.e., a 180° curve and particularly preferred that the generally circular curve form a full
30 circle, i.e. 360°.

The generally circular curve of the tip portion 12 may be positioned relative to the axis of the catheter body 11 so that the axis A of the catheter
body 11 lies on the perimeter of the generally circular curve as shown in FIG. 2 or at any point within the generally circular curve, for example as shown in FIG.
35 3.

The tubular wall of the tip portion 12, may be made of any suitable material. It is more compressible and preferably, more flexible, i.e., bendable,

1 than the catheter body 11. A presently preferred construction for the catheter
tip portion 12 comprises a thermoplastic resin, e.g., polyurethane, reinforced
with a dacron braid. The diameter of the catheter tip portion 12 is not critical,
but is preferably about the same as or slightly smaller than the diameter of the
5 catheter body 11.

The compound curve of the catheter tip portion 12 can be formed by any
suitable process. In a preferred embodiment, the tubular wall of the tip portion
comprises a thermoplastic resin. The catheter is first constructed, e.g.,
mounting or formation of the electrodes, attachment of the puller wire, etc.,
10 without the compound curve in the tip portion, i.e., with the tip portion being
straight. The tip portion is then inserted into a tubular, generally rigid form 40
as shown in FIG. 8. The form 40 which may be made of any suitable material,
e.g., nylon, has the shape of the desired compound curve. The tip portion of
the catheter and the holder are then heated to a temperature sufficient for the
15 tip portion to acquire the shape of the form 40 and to retain that shape when
cooled. The form 40 can also be used to contain the tip portion 12 when the
catheter is not in use to prevent damage or stress to the tip portion 12.

Along the length of the generally circular section 18 of the tip portion 12,
there are a plurality of electrodes 21. The electrodes may be single electrodes
20 or electrode pairs. The electrodes 21 may be in the form of metal rings, the
outer diameter of the electrodes 21 being about the same as the outer diameter
of the flexible tubing of the tip portion 12 so that the electrodes 21 form a
smooth, continuous surface with the outer surface of the flexible tubing.
Electrode lead wires 22 having an insulation coating extend from the electrodes
25 21 through the lumen 16 and 15 of the catheter tip portion 12 and the catheter
body 11 and the handle is electrically connected to molded multi-pin connectors
23. The connectors 23 may be plugged directly into a stimulator/recorder or
other electrical device or connected to the female end to a floating extension
cable which in turn has connectors at its opposite end which can be plugged into
30 the electrical device. It is apparent that the lead wires may be connected to a
rotary plug or to individual tip pins if desired.

Alternatively, the electrodes 21 may be formed by passing the electrode
lead wires 22 through the wall of the catheter tip portion 12 at separate
locations and wrapping the lead wires 22 around the tubing as shown in FIG. 4.
35 The wrapped wires are secured to the wall of the tip portion by adhesive or other
suitable means. The insulation coating of the lead wires 22 is stripped off those
portions of the wrapped wires which will contact the heart wall. Such a

1 construction is described in U.S. Patent Application Serial No. 07/906,546, filed
June 30, 1992, which is incorporated herein by reference.

5 In the embodiment shown, the catheter tip portion 12 carries ten wound
electrode pairs 21. Three platinum locator rings or markers 25 are placed
equidistant between the fifth and sixth electrode pairs and bordering each end
of the electrode array. The marker 25 can be easily distinguished from the
electrode pairs under fluoroscopy. This enables identification of the position of
each electrode during a mapping procedure. It is understood that the number of
electrodes vary as required. The number, location and even presence of a marker
10 or markers is optional.

A puller wire 30, preferably made of stainless steel, extends from the
control hand 13 through the lumen 15 of the catheter body 11 and into the
lumen 16 of the catheter tip portion 12. In the embodiment shown, the puller
wire 30 extends through the lumen 16 of the catheter tip portion 12 and is
15 fixedly attached to the distal tip of the tip portion 12. A preferred anchor means
for attaching the puller wire 30 to the catheter tip portion 12 is described in U.S.
Patent No. 4,960,134 which is incorporated herein by reference.

20 With reference to FIG. 9, there is shown a presently preferred method of
attachment. An anchor 41 is fixedly attached, e.g., crimped to the distal end of
the puller wire 30. The anchor 41 is then wedged against the tip portion wall
and secured at the distal tip of the tip portion by means of plug 42 which is
fixed, e.g., glued, in place. The plug 42 and any exposed edges of the anchor
41 are preferably covered with a suitable resin material 43, or the like, to form
a rounded distal tip.

25 Any suitable control handle 13 which can control longitudinal movement
of the puller wire 30 relative to the catheter body 11 may be used. A preferred
control handle 13, as shown in FIG 1, is described in U.S. Patent No. 4,960,134
which is incorporated herein by reference.

30 Movement of the puller wire 30 rearwardly or proximally relative to the
catheter body 11 by manipulation of the control handle 13 results in a tightening
of the compound curve of the tip portion 12. Specifically, the bend in the first
section of the tip portion 12 becomes more acute and the diameter of the
generally circular curve of the second section of the tip portion 12 decreases.
FIG. 4 shows the catheter tip portion 12 in its normal state, i.e., before the puller
35 wire 30 is moved proximally relative to the catheter body 11. FIG. 5 shows the
effect on the tip portion 12 of moving the pulling wire 30 proximally relative to
the catheter body 11.

1 In use, the catheter 10 is preferably inserted into the femoral vein by
conventional technique and is advanced through the inferior vena cava 31 into
the right atrium 32. The distal end of the tip portion of the catheter is
5 maneuvered into the coronary sinus ostium 35 and the generally circular section
of the tip portion is maneuvered so as to lie about the periphery of the tricuspid
valve 36. Heretofore, such maneuvering has been difficult and time consuming.
The ability to adjust the diameter of the generally circular section of the tip
portion greatly enhances the ability to accomplish the desired maneuvers. It also
10 allows the generally circular section of the tip portion to be adjusted to better
fit the varying sizes of heart patients.

The preceding description has presented with reference to a presently
preferred embodiment of the invention shown in the drawings. Workers skilled
in the art and technology to which this invention pertains will appreciate that
alterations and changes in the described structures can be practiced without
15 meaningfully departing from the principal, spirit, and scope of this invention.

Accordingly, the foregoing description should not be read as pertaining
only to the precise structures described and shown in the accompanying
drawings, but rather should be read consistent with and as support to the
following claims which are to have their fullest and fair scope.

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1 What is Claimed Is

1. An elongated electrode catheter comprising:
an elongated flexible tubular catheter body having proximal and
distal ends;
5 a tubular tip portion at the distal end of the tubular body forming
a generally circular curve transverse to the axis of the catheter body, said tip
portion carrying a plurality of spaced apart electrodes;
an electrode lead wire associated with each electrode, said
electrode lead wire extending through the catheter body and into the catheter tip
10 portion, the distal end of the electrode lead wire being electrically connected to
its associated electrode;
a puller wire having proximal and distal ends extending through the
tubular body and into the tip portion the distal end of the puller wire being fixedly
attached to about the distal end of the tip portion, whereby longitudinal
15 movement of the puller wire relative to the tubular body results in contraction of
the generally circular curve of the tip portion at the proximal end of the tubular
body means for moving the puller; and
handle means connected to the proximal ends of the catheter body
and puller wire for moving the puller wire longitudinally relative to the catheter
20 body to thereby control the diameter of the generally circular curve of the tip
portion.
2. An electrode catheter as claimed in claim 1, wherein the plane of
the generally circular curve of the tip portion is at an angle of about 30° to the
25 axis of the tubular catheter body.
3. An electrode catheter as claimed in claim 1, wherein the tip portion
comprises a compound curve having a first bend away from the axis of the
catheter body and a second bend forming a generally circular curve transverse
30 to the axis of the catheter body.
4. An electrode catheter as claimed in claim 3, wherein the first bend
is approximately 30°.

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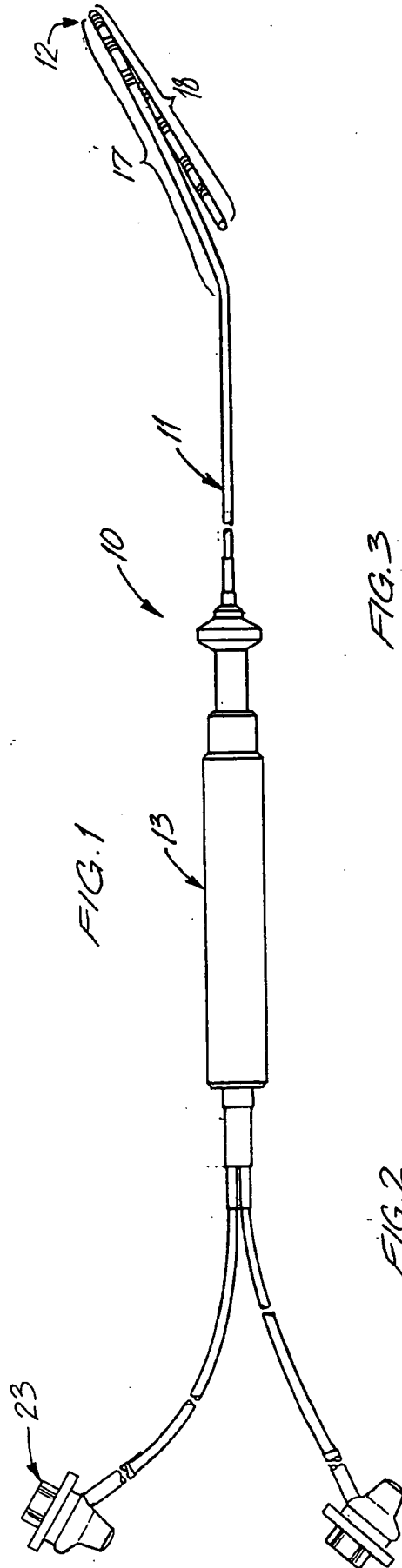


FIG. 3

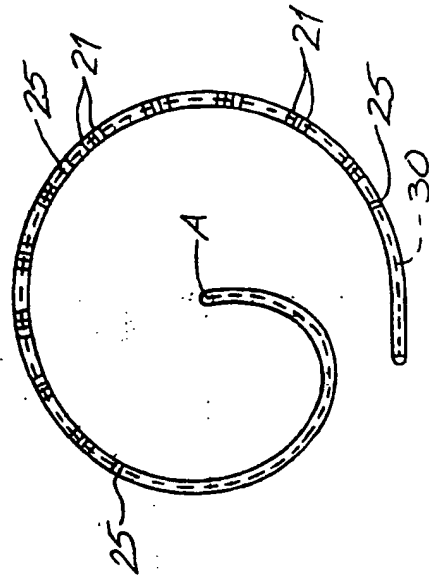
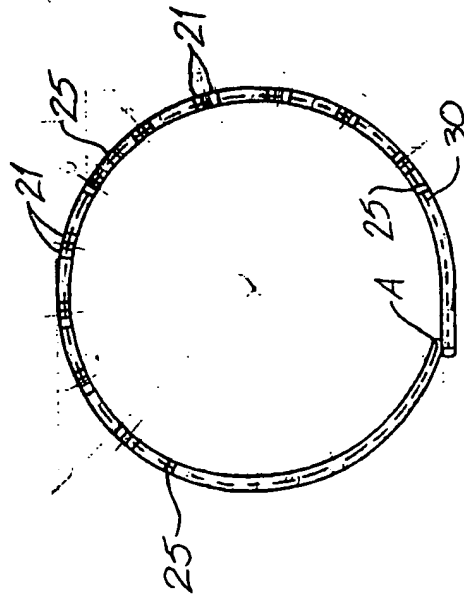


FIG. 2



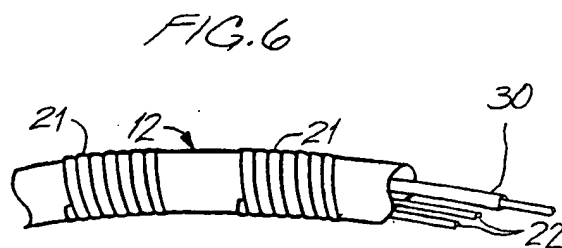
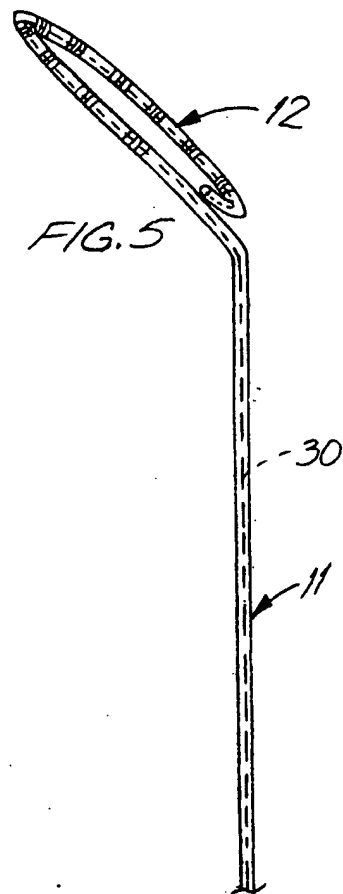
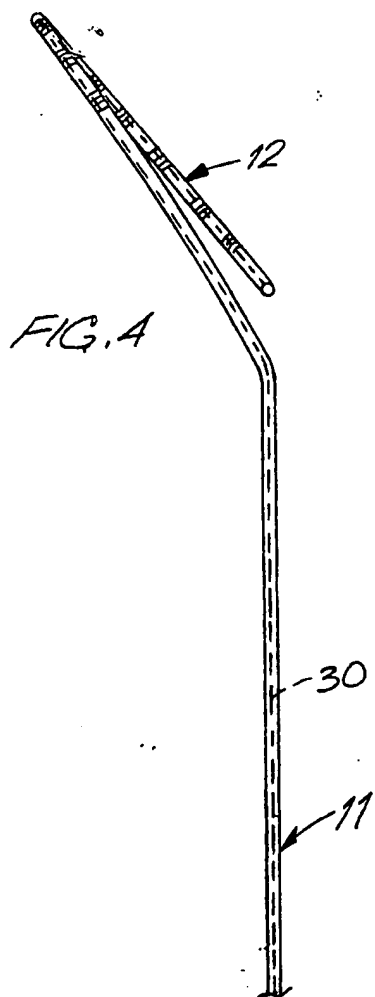


FIG. 7

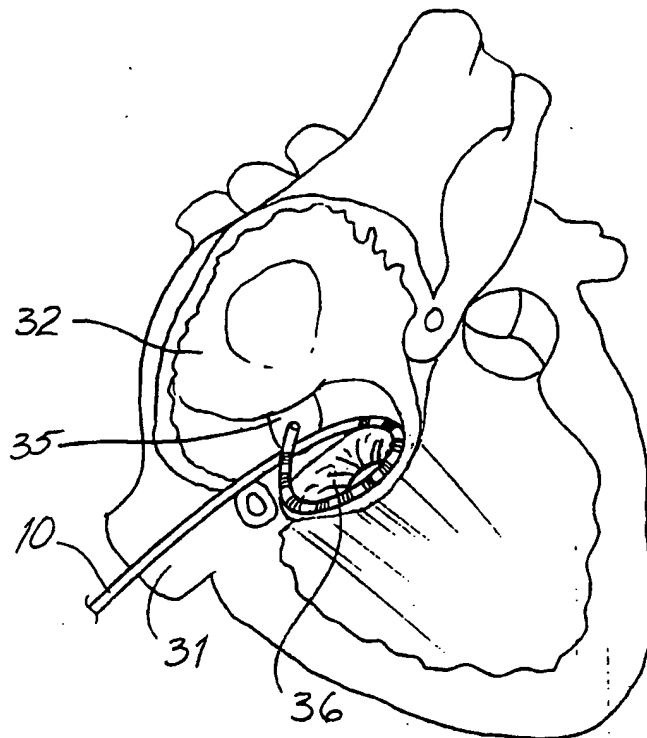


FIG. 8

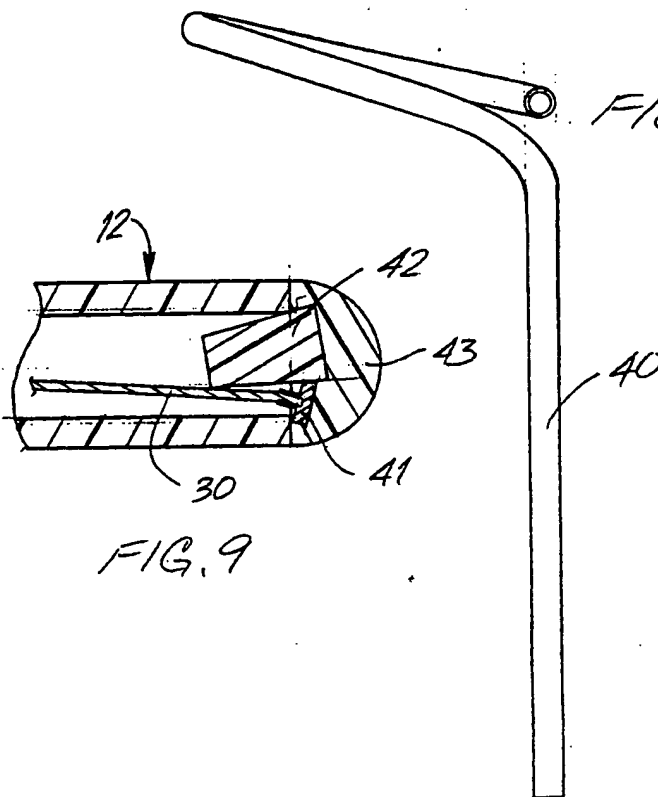
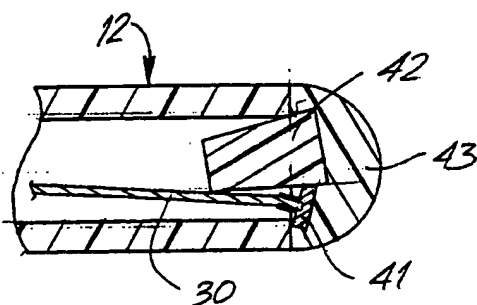


FIG. 9



INTERNATIONAL SEARCH REPORT

International application No:
PCT/US94/04699

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 5/04

US CL :128/642, 772; 606/129; 607/125

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/639, 642, 772; 606/129; 607/116, 119, 122, 125

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,777,955, (BRAYTON ET AL.), 18 October 1988. See entire document.	1-4
A	US, A, 4,960,134, (WEBSTER, JR.), 02 October 1990. See entire document.	1-4
A, P	US, A, 5,255,679, (IMRAN), 26 October 1993. See entire document.	1-4
X ---, P Y	US, A, 5,263,493, (AVITALL), 23 November 1993. See entire document.	1, 3 ----- 2, 4
A, P	US, A, 5,275,162, (EDWARDS ET AL.), 04 January 1994. See entire document.	1-4



Further documents are listed in the continuation of Box C.



See patent family annex.

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